Remarks:

This amendment is submitted in an earnest effort to advance this case to issue without delay.

The priority papers were filed with the original application papers and their receipt was acknowledged in the above-mentioned Examiner's Action. The undersigned hereby reiterates the priority claim made in the earlier-filed Declaration.

The claims have been amended to emphasize the novelty of the invention. More particularly the claims make lucidly clear that the pressure inside the container (typically a syringe) is monitored separately from the temperature in the autoclave outside the container. In addition a new claim 17 has been added that states that the pressure in the autoclave chamber is varied "continuously" (see the Abstract) in accordance with the output of the actual pressure inside the container in the chamber.

It is important to note that the pressure inside the container is not normally the same as that in the autoclave outside the container. In the simplest embodiment where the container is a syringe holding some water, once the water is turned into steam, the pressure inside the container will, unless relieved, be much higher than the pressure surrounding the container in the autoclave chamber.

In the primary reference, US patent 5,439,643 of Liebert, a calculated guess is made as to the level to which the pressure is going to rise inside the container being autoclaved, and the pressure in the autoclave container around the container is raised to this level. In this manner the plunger of a syringe being autoclaved will not be pushed out the end.

More particularly as described in column 5, starting at line 10 of Liebert:

> After loading the prefilled packages into the air sterilization vessel, the vessel is sealed shut, appropriate pressure is applied to the chamber to prevent package failure during the sterilization process. Next, the device for heating the air in the sterilization chamber is implemented. By monitoring the load and chamber temperature through the use appropriate temperature sensing devices such as RTDs, thermocouples or thermistors, the operator can determine when the load has had the necessary exposure... During the exposure ... the formulation produces steam and pressure in response to the applied heat. When adequate exposure time has been attained, the applied heat may be discontinued so that the load can start to cool.

The only pressure that is monitored in Liebert is the pressure in the autoclave around, that is outside, the container being sterilized. Thus Liebert represents the exact state of the

prior art as described in the first paragraph of the Background of the Invention of this application, namely pressurizing an autoclave chamber to a predetermined superatmospheric pressure during the sterilizing operation.

The problem with this method is that it is necessary to conduct extensive tests with the materials being autoclaved to determine just what pressure is needed. In addition the rate at which the pressure increases as the product is heated and the rate at which it decreases as it is cooled are critical if one is to minimize stress to the container. For instance if the liquid contains a solvent, e.g. alcohol, with a low boiling point, the pressure will rise in the container at a lower temperature, while with a container having a fairly massive charge, the temperature will drop more slowly.

Establishing, as Liebert does, a predetermined superatmospheric pressure in the autoclave chamber at the start of the operation means that, for instance, a plunger of a syringe containing some liquid and gas, will shift inward at the start of the cycle. As the liquid in the syringe vaporizes and the gas in the syringe heats up, the plunger will move back out either to or past the starting position, and when the system cools down the plunger will shift back more or less to its starting position. In fact Liebert makes it clear that, with a syringe, there is always some shifting of the plunger during the autoclaving process.

With the instant invention the *actual pressure inside the container* is monitored during the operation and the *actual pressure outside the container* is varied to be the same. Thus with a syringe the plunger will not shift at all. This ensures that the autoclaving process will not damage the product at all.

Furthermore the system of this invention, by *responding to actual conditions* is much easier to operate. There is no need to adjust the pressure for each product being sterilized, only the maximum pressure and treatment time need be set. Thus not only is the system of the instant invention simpler to use, but it also works better.

No rejection of the claims of this case under §102 on Liebert is possible because Liebert does not teach the step of monitoring the pressure inside the container. At best, Liebert has some idea of the pressure inside the container based on the pressure and temperature outside the container, but this gives at best an approximation of the pressure inside the container and does not comprise the step of "monitoring" but is more accurately a calculation step. There is no suggestion or hardware shown to suggest monitoring the pressure inside the container, like the plunger-watching light curtains of the instant invention, so that a §103 rejection on Liebert is also impossible.

While US patent 6,422,084 of Fernald does indeed show an optical system that in theory could be used to detect the position

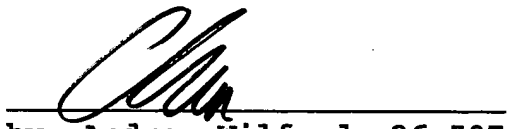
of a plunger of a syringe in an autoclave, there is no suggestion anywhere in the art to do so. Combining the teachings of Fernald with those of Liebert is not obvious because Liebert liberally admits that the syringe plunger can shift and that this is not a problem or anything that needs to be monitored, so long as the plunger has space to shift somewhat during the autoclaving operations. A §103 rejection on Liebert or Fernald cannot stand.

Similarly, if there were somewhere a suggestion to monitor pressure inside the syringe, perhaps the combination of Liebert and the teachings of US patent 6,394,977 of Taylor would be obvious. This is, however, not the case. No-one suggests monitoring the pressure inside a container being autoclaved and varying the pressure outside to correspond to it. At best the art suggests applying outside the container a pressure that is hopefully about equal to the pressure inside it at some time during the autoclave operation, but no-one actually proposes eliminating the guesswork and not only actually monitoring the pressure inside the autoclaved container, but also dynamically varying the pressure outside to be the same as this actual-value signal. Taylor also does not combine with Liebert to form a valid §103 rejection.

For these reasons all the claims in the case are clearly in condition for allowance. Notice to that effect is earnestly solicited.

If only minor problems that could be corrected by means of a telephone conference stand in the way of allowance of this case, the examiner is invited to call the undersigned to make the necessary corrections.

Respectfully submitted,
The Firm of Karl F. Ross P.C.



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